

## **REMARKS**

Claims 1-44 are now pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **OBJECTION TO DRAWINGS OR SPECIFICATION**

The drawings stand objected to for certain informalities, specifically because the character 163 shown in FIG. 16 is not mentioned in the specification. Applicants have revised paragraph [0043] of the specification to include character 163 for the plane described in line 5 of paragraph [0043] and shown in FIG. 16 with character 163.

Reconsideration and withdrawal of this objection is respectfully requested.

### **CLAIM OBJECTIONS**

Claims 16, 18, 25, 29, and 41 are objected to because of certain informalities regarding inconsistent terminology. Applicant has amended Claims 16, 18, 25, 29, and 41 according to the Examiner's suggestions. Therefore, reconsideration and withdrawal of these objections are respectfully requested.

### **REJECTION UNDER 35 U.S.C. § 112**

Claims 17-21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. Claim 17 was amended as suggested by the Examiner. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lombardo et al. (U.S. Pub. No. 2004/0127896 A1) in view of Konieczynski et al. (U.S. Pub. No. 2004/0127899 A1). This rejection is respectfully traversed.

As a first matter, the Office Action states that Lombardo et al does not disclose an expandable head member, and cites Konieczynski et al for disclosing an expandable head member. Applicants disagree that Konieczynski et al can be combined with Lombardo et al to provide an expandable head member. Lombardo et al includes a washer, which can also be a split ring, Fig. 31. The washer or split ring of Lombardo et al are structured to engage with the head of the fastener in particular ways, as described below, and cannot be replaced by other washers, such as the washer of Konieczynski et al, without destroying the structure and function of the implant of Lombardo et al. Furthermore, Lombardo et al discloses in certain embodiments deformable washers adapted for use with its fastener. See paragraph [0071].

Regarding independent claim 1, Lombardo et al fails to disclose a shaft with an outer cam that is defined by a continuous curve of continuous slope and variable radius. Further, Lombardo et al fails to disclose that the outer cam mates with an inner cam of the head member, wherein the inner cam is defined by a continuous curve of continuous slope and variable radius. On the contrary, Lombardo et al discloses a central opening 125 with continuously sloped lobes 126, however these lobes 126 do not mate with corresponding cams or lobes of the shaft of the fastener. Rather, a tool provided with a head adapted to fit within the central washer opening 125 and lobes 126 is inserted into the washer, for rotating the washer. See paragraph [0069], lines 11-13.

The washer is connected with the head of the fastener such that discontinuous wedges 122 defined by tangs 120 of the head of the fastener mate with track portions 128 defined in splays 127 of the washer. Konieczynski et al, even if combinable with Lombardo et al, fails to provide these missing elements. Accordingly, independent claim 1 is patentable over Lombardo et al. in view of Konieczynski et al. Claims 2-16 ultimately depend from claim 1 and are, at least for this reason, also patentable over Lombardo et al in view of Konieczynski et al.

Regarding independent claim 17, Lombardo et al fails to disclose a shaft cam lobe mating with a head cam lobe, the shaft and head cam lobes defined by continuously curved surfaces and having continuous slopes, for the reasons discussed above. Konieczynski et al, even if combinable with Lombardo et al, fails to provide these missing elements. Accordingly, independent claim 17 is patentable over Lombardo et al in view of Konieczynski et al. Claims 18-21 ultimately depend from claim 17 and are, at least for this reason, also patentable over Lombardo et al in view of Konieczynski et al.

Similarly, regarding independent claims 22 and 28, Lombardo et al fails to disclose mating first and second cams, each defined by a continuous curve of variable radius and continuous slope, for the reasons discussed above. Konieczynski et al, even if combinable with Lombardo et al, fails to provide these missing elements. Accordingly, independent claims 22 and 28 are patentable over Lombardo et al. in view of Konieczynski et al. Claims 23-27 ultimately depend from claim 22 and are, at least for this reason, also patentable over Lombardo et al. in view of Konieczynski et al. Claims

29-36 ultimately depend from claim 28 and are, at least for this reason, also patentable over Lombardo et al in view of Konieczynski et al.

Regarding independent claim 37, Lombardo et al fails to disclose an expandable head member that in a first position has a maximum diameter that is smaller than the first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter. On the contrary, in all the embodiments described in Lombardo et al, the head 20 of the bone screw is described as being sized such that it does not pass through the bone plate 12. See, for example, paragraph [0056], lines 7-8. The bone screws are inserted through apertures in the washers and can pass therethrough. See [0063] lines 4-15. Accordingly, the washer cannot have a maximum diameter that is smaller than the diameter of the fixation hole in any position. Therefore, Lombardo et al teaches away from expandable washers that have a maximum diameter that is smaller than the diameter of the fixation hole in any position, and cannot be combined with any other references, to provide this element, or with Konieczynski et al, even assuming without conceding that Konieczynski et al provides this element. Accordingly, independent claim 37 is patentable over Lombardo et al. in view of Konieczynski et al. Claims 38-41 ultimately depend from claim 37 and are, at least for this reason, also patentable over Lombardo et al. in view of Konieczynski et al. Further, at least claim 40 is independently patentable over Lombardo et al in view of Konieczynski et al because it adds the elements of mating shaft and head cams, each cam defined by a continuous curve of variable radius and continuous slope, as discussed above.

Reconsideration and withdrawal of the rejections of claims 1-41 is respectfully requested.

**NEW CLAIMS**


Claims 42-44 are new and are fully supported by the specification and drawings as originally filed. Applicants respectfully submit that claims 42-44 are in condition for allowance.

**CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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By:   
Stephen T. Olson  
Reg. No. 36,626  
Maria Comninou  
Reg. No. 44,626

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

STO/MAC/sms